

REMARKS

Reconsideration of the above-identified application in view of the amendment above the remarks below is respectfully requested.

No claims have been canceled or added in this paper. Claims 12, 22, 27, 29 and 30 have been amended in this paper. Therefore, claims 12, 22, 27, 29 and 30 are pending and are under active consideration.

Claims 12, 22, 27, 29 and 30 stand rejected under 35 U.S.C. 101 “because the claimed invention is directed to non-statutory subject matter.” In support of the rejection, the Patent Office states the following:

The recent en banc decision regarding *Bilski v. Warsaw* (2008) set forth that a process is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing. Further, the recent decision in *Comiskey* (2009) confirmed the opinion set forth in *Bilski* of the prohibition pre-empting an abstract idea or mental process in a claim. The revised *Comiskey* decision further reiterated the precedent set forth in *Richman*, 563, F.2d 1026, 1030 (CCPA 1977) wherein the court held the application unpatentable because “if a claim [as a whole] is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.”

In the instant case, the claims are directed to a method of determining a biological effect and/or activity of at least one pharmaceutical composition. The recited process involves the steps of obtaining biological samples A and B, analyzing the level of cytosine methylation therein, selecting chosen sites that are differentially methylated, and concluding from a knowledge database a biological effect or activity. Said claims do not recite any step wherein an active physical transformation of a particular article takes place. Rather, the instant claims only require obtaining samples in a particular condition for analysis of their respective state of

methylation. The analysis recited in the instant claims does not require physical transformation of an article. Further, the selection and conclusion steps read only on an abstract series of mental processes. The ultimate conclusion wherein a conclusion is communicated via the internet or intranet is further treated as insignificant post-solution activity since the communication of a result does not impact the earlier steps wherein said result is determined.

Therefore, the examiner must determine if the instant claims have a tie to a particular machine or apparatus. In the instant case, the claims do not recite any tie to a machine other than the ultimate step of communicating a conclusion to a computer via an internet or intranet connect. However, as indicated above, the final step of communicating a result has been treated as an insignificant, post-solution activity step.

For these reasons, the instant claims are directed to non-statutory subject matter.

For the benefit of applicant, the instant rejection could be overcome by amendment to the instant claims so as to recite active sample preparation steps whereby the "obtaining" steps require exposure of a pharmaceutical sample and the transformation of said sample methylation state. Further, the instant rejection could be overcome by amendment wherein the "analysis," "selection" and "conclusion" steps expressly recite the use of a suitably programmed computer. Applicants are further cautioned against the introduction of new matter and are requested to cite support from the instant specification for all claim amendments.

Applicants respectfully traverse the subject rejection. Without acquiescing in the propriety of the subject rejection, Applicants have amended claims 12, 22, 27, 29 and 30 in the fashion suggested by the Patent Office to obviate the rejection, namely, by specifying that the analysis, selection and conclusion steps are performed using a suitably programmed computer. Support for this limitation may be found in the present specification, for example, on page 10, first full paragraph, on page 14,

first full paragraph, in the paragraph bridging pages 14 and 15, and on page 15, third full paragraph.

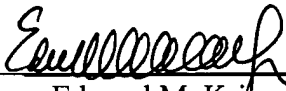
Accordingly, the rejection has been obviated and should be withdrawn.

In conclusion, it is respectfully submitted that the present application is now in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

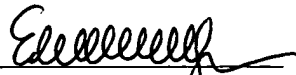
Respectfully submitted,

Kriegsman & Kriegsman

By: 
Edward M. Kriegsman
Reg. No. 33,529
30 Turnpike Road, Suite 9
Southborough, MA 01772
(508) 481-3500

Dated: December 9, 2009

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 9, 2009


Edward M. Kriegsman